IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: AHARONI=5B In re Application of: Conf. No.: 6949 1646 Rina AHARONI et al Art Unit: RECEIVED Appln. No.: 09/831,629 Examiner: Washington, D.C. Filed: August 17, 2001 MAR n 4 2003 March 3, 2003 For: PHARMACEUTICAL TECH CENTER 1600|2900 COMPOSITIONS COMPRISING SYNTHETIC PEPTIDE ...

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents Washington, D.C. 20231

Sir:

MAR 0 3 2003

This Information Disclosure Statement is submitted in accordance with 37 CFR §\$1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR \$1.97, as it is filed:

(Check one of the boxes A-D)

- [] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- [A] B. before the mailing date of a first office action on the merits.

[] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "i" below).

(Check one of the boxes "i" and "ii" below:)

- [] i. Counsel certifies that, upon information and belief, each item of information listed herein was either
 - [] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
 - [] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in \$1.56(c) more than three months prior to the filing of this IDS.

(use one and delete other of following)

- [] ii. A check (check no. _____) for the fee set forth in \$1.17(p), presently believed to be \$180, is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.
- [] ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in \$1.17(p), presently believed to be \$180. If the enclosed payment is incorrect,

please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

- payment of the issue fee: Applicant(s) petitions under 37 CFR \$1.97(d) for consideration of this IDS. (use one and delete other of following and this note) A check (check no. _____) for/ Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in \$1.17(i), presently believed to be \$130 is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035. Counsel certifies that, upon information and belief, each item of information listed herein was either
 - [] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
 - [] (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in \$1.56(c) more than three months prior to the filing of this IDS.
- [X] 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an

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attachment hereto. A copy of each document listed is attached, except as explained below. [] A. Document(s) _____ is (are) substantially cumulative to document(s) _____, and, in accordance with \$1.98(c), only a copy of each of the latter documents is enclosed. [] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120: (insert serial numbers and filing dates of prior applications) Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449/SB-08A from the files of the prior application(s) or a fresh PTO-1449/SB-08A listing these documents, and request that they be considered and made of record in accordance with \$1.98(d). Per 37 CFR \$1.98(d), copies of these documents need not be filed in this application. [] 3. Document(s) _____ is (are) not in the English language. In accordance with \$1.98(c), Applicant(s) states: [] An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed. [] A concise explanation of the relevance of document(s) is found in the attached search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20). [] A concise explanation of the relevance of document(s) _____ is set forth as follows:

In re Appln. No. 09/831,629

(insert concise explanation of relevance)

- [] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- [] A concise explanation of document(s) _____ can be found on the attached sheet.
- [X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [] 5. Other information being provided for the examiner's consideration follows:

(insert other information)

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK

Attorneys for Applicant(s)

By:

Roger L. Browdy Reg. No. 25,618

RLB:rd

624 Ninth Street, N.W., Suite 300

Washington, D.C. 20001-5303

Telephone: (202)628-5197 Facsimile: (202)737-3528



Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known		
Application Number	09/831,629	
Filing Date	August 17, 2001	
First Named Inventor	Rina AHARONI	
Group Art Unit	1646	
Examiner Name		
Attorney Docket Number	AHARONI=5B	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the Cite xaminer item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published AHARONI et al, "Copolymer 1 induces T cells of the T helper type 2 that crossreact with myelin basic protein and suppress experimental autoimmune encephalomyelitis", <u>Proc Natl Acad Sci USA</u> 94(20):10821-10826 (1997) ARNON et al, "New insights into the mechanism of action of copolymer 1 in experimental allergic encephalomyelitis and multiple sclerosis", <u>J Neurol</u> 243(4 Suppl 1):S8-13 (1996) JOHNSON et al. "Copolymer 1 reduces relapse rate and improves disability in relapsing-remitting multiple sclerosis: results of a phase III multicenter, double-blind, placebo-controlled trial", Neurology 45:1268-1276 SCHLEGEL et al, "Prevention of graft-versus-host disease by peptides binding to class II major histocompatibility complex molecules", Blood 84(8):2802-2810 (1994) TEITELBAUM et al, ""Development of Copolymer 1 (Copaxone®) as a Specific Drug Against Multiple Sclerosis", in <u>The Decade of Autoimmunity</u>, Y. Shoenfeld, ed., Elsevier Science B.V., pp 191-196 (1999) RECEIVED MAR N 4 7003 **TECH CENTER 1600/2900**

Examiner	Date	
Signature	Considered	

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.